

Amendments To The Specification

In the Specification

Please amend the **Brief Description of the Drawings** at page 13 of the specification as follows to insert SEQ ID NOs

Please replace the paragraph at page 13, lines 26-27, with the following rewritten paragraph:

--Figures 42A-42D shows human SCF cDNA sequence (SEQ ID NOs:60 AND 61) obtained from the HT1080 fibrosarcoma cell line.--

Please replace the paragraph at page 13, lines 33-34 with the following rewritten paragraph:

--Figures 44A-44C shows human SCF cDNA sequence (SEQ ID NOs:62 AND 63) obtained from the 5637 bladder carcinoma cell line.--

Please amend the **Detailed Description of the Preferred Embodiments** as follows:

At page 182, paragraph 1, please replace the paragraph between lines 5 and 28 with the following rewritten paragraph, which is presented to update the status of application referenced therein:

--Plasmid constructions for expression of numerous SCF analogs and fragments have been made. Site-directed mutagenesis had been used to prepare plasmids with initiating methionine codon followed by codons for amino acids 1 to 178, 173, 168, 166, 163, 162, 161, 160, 159 158 157 156 148 145 141 137, using the numbering of Figure 15C. The DNA for human SCF¹⁻¹⁸³ (Example 6B) was cloned into MP11 from Xba1 to BamH1. Phage from this cloning was used to transfect an *E. coli* dut⁻ ung⁻ strain, R21032. Single stranded M13 DNA was prepared from this strain and site-directed mutagenesis was performed (reference IL-2 patent). After the site-directed mutagenesis reactions, the DNAs were transformed into an *E. coli* dut⁺ ung⁺ strain, JM101. Clones were screened and sequences as described in copending U.S. application Serial No. 717,334, filed March 29, 1985, now abandoned. Plasmid DNA preps were

made from positive clones and the SCF regions from Xba1 to BamH1 were cloned into pCFM1656 as described in copending U.S. patent application Serial No. 501,904, filed March 29, 1990, now abandoned. The oligonucleotides for each cloning were designed to substitute a stop codon for an amino acid codon at the appropriate position for each analog.--

Complete Listing of Claims Pursuant to 37 C.F.R. §1.121

Pursuant to 37 C.F.R. §1.121 the following is a complete listing of the claims of the present application. In this set of claims, please amend the claims as follows. With the amendments to the claims, the following listing of claims will replace all prior versions, and listings, of claims in the application:

Claims 1-70 [Canceled]

71. [currently amended] A method of stimulating ~~growth~~ proliferation or differentiation of melanocyte ~~precursor~~ cells in a human, the method comprising the step of administering to the human, an amount of a human stem cell factor (SCF) polypeptide and optionally a pharmaceutically acceptable carrier.

72. [previously presented] The method of claim 71 wherein stem cell factor polypeptide selected is selected from the group consisting of amino acids 1-162, 1-164, and 1-165 as set out in SEQ ID NO: 46, said polypeptide optionally consisting of an N-terminal methionine.

73. [currently amended] The method of claim 71 wherein the stem cell factor polypeptide is selected from the group consisting of amino acids ~~1-100, 1-110, 1-120, 1-123, 1-127, 1-130, 1-133, 1-137, 1-141, 1-145, 1-148, 1-152, 1-156, 1-157, 1-158, 1-159, 1-160, 1-161, 1-163, 1-166, 1-168, 1-173, 1-178, 2-164, 2-165, 5-164, 11-164, 1-180, 1-183, 1-185, 1-188, 1-189, 1-220, and 1-248~~ as set out in SEQ ID NO: 61, said polypeptide optionally consisting of an N-terminal methionine.

74. [previously presented] The method of claim 71 wherein the stem cell factor polypeptide is selected from the group consisting of amino acids 1-152, 1-157, 1-160, 1-161, and 1-220 as set out in SEQ ID NO: 63, said polypeptide optionally consisting of an N-terminal methionine.

75. [currently amended] A method of treating a ~~pigmentation~~ hypopigmentation disorder in a human, the method comprising the step of administering to the human, a therapeutically effective amount of a stem cell factor (SCF) polypeptide, and optionally a pharmaceutically acceptable carrier.

76. [previously presented] The method of claim 75 wherein the stem cell factor polypeptide is selected from the group consisting of amino acids 1-162, 1-164, and 1-165 as set out in SEQ ID NO: 46, said polypeptide optionally consisting of an N-terminal methionine.

77. [previously presented] The method of claim 75 wherein the stem cell factor polypeptide is selected from the group consisting of amino acids ~~1-100, 1-110, 1-120, 1-123, 1-127,~~ 1-130, 1-133, 1-137, 1-141, 1-145, 1-148, 1-152, 1-156, 1-157, 1-158, 1-159, 1-160, 1-161, 1-163, 1-166, 1-168, 1-173, 1-178, 2-164, 2-165, 5-164, 11-164, 1-180, 1-183, 1-185, 1-188, 1-189, 1-220, and 1-248 as set out in SEQ ID NO: 61, said polypeptide optionally consisting of an N-terminal methionine.

78. [previously presented] The method of claim 75 wherein the stem cell factor polypeptide is selected from the group consisting of amino acids 1-152, 1-157, 1-160, 1-161, and 1-220 as set out in SEQ ID NO: 63, said polypeptide optionally consisting of an N-terminal methionine.

79. [previously presented] The method of claim 71 or 75 wherein the stem cell factor is covalently conjugated to a water soluble polymer.

80. [previously presented] The method of claim 79 wherein the water soluble polymer is polyethylene glycol.

81. [previously presented] The method of claim 71 or 75 wherein the stem cell factor is co administered with at least one other cytokine.

82. [previously presented] The method of claim 79 wherein the stem cell factor is co administered with at least one other cytokine.

83. [previously presented] The method of claim 81 wherein one or more cytokines are selected from a group consisting of Interleukin-1 (IL-1), Interleukin-2 (IL-2), Interleukin-3 (IL-3), Interleukin-4 (IL-4), Interleukin-5 (IL-5), Interleukin-6 (IL-6), Interleukin-7 (IL-7), Interleukin-8 (IL-8), Interleukin-9 (IL-9), Interleukin-10 (IL-10), Interleukin-11 (IL-11), Interleukin-12 (IL-12), erythropoietin (EPO), Granulocyte Colony-stimulating Growth Factor (G-CSF), Macrophage Colony-Stimulating Factor (M-CSF), Granulocyte-Macrophage Colony-Stimulating Factor (GM-CSF), Insulin-like Growth Factor-1 (IGF-1), and Leukemic Inhibitory Factor (LIF).

84. [previously presented] The method of claim 82 wherein one or more cytokines are selected from a group consisting of IL-1, IL-2, IL-3, IL-4, IL-5, IL-6, IL-7, IL-8, IL-9, IL-10, IL-11, IL-12, EPO, G-CSF, M-CSF, GM-CSF, IGF-1, and LIF.

85. [previously presented] The method of claim 71 wherein the pharmaceutically acceptable carrier is suitable for topical delivery.

86. [previously presented] The method of claim 71 wherein the pharmaceutically acceptable carrier is suitable for oral delivery.

87. [previously presented] The method of claim 71 wherein the pharmaceutically acceptable carrier is suitable for parenteral delivery.

88. [previously presented] The method of claim 71 wherein the pharmaceutically acceptable carrier is suitable for pulmonary delivery.

89. [previously presented] The method of claim 71 wherein the pharmaceutically acceptable carrier is suitable for nasal delivery.

90. [previously presented] The method of claim 75 wherein the pharmaceutically acceptable carrier is suitable for topical delivery.

91. [previously presented] The method of claim 75 wherein the pharmaceutically acceptable carrier is suitable for oral delivery.

92. [previously presented] The method of claim 75 wherein the pharmaceutically acceptable carrier is suitable for parenteral delivery.

93. [previously presented] The method of claim 75 wherein the pharmaceutically acceptable carrier is suitable for pulmonary delivery.

94. [previously presented] The method of claim 75 wherein the pharmaceutically acceptable carrier is suitable for nasal delivery.

95. [currently amended] The method of claim 75 wherein the ~~pigmentation~~ hypopigmentation disorder is melanocytopenia.

96. [previously presented] The method of claim 75 wherein the melanocytopenia is selected from the group consisting of vitilago and piebaldism.

97. [new] A method of stimulating proliferation or differentiation of melanocyte cells in a human, the method comprising the step of administering to the human, an amount of a SCF polypeptide having the amino acid sequence of SEQ ID NO:44, SEQ ID NO: 46, or SEQ ID NO: 63, or biologically active fragments thereof that stimulate growth of hematopoietic progenitor cells, and optionally a pharmaceutically acceptable carrier.

98. [new] A method of treating a hypopigmentation disorder in a human, the method comprising the step of administering to the human, a therapeutically effective amount of a SCF polypeptide having the amino acid sequence of SEQ ID NO:44, SEQ ID NO: 46, or SEQ ID NO: 63, or biologically active fragments thereof that stimulate growth of hematopoietic progenitor cells,, and optionally a pharmaceutically acceptable carrier.

99. [new] The method of claim 97 or 98 wherein the stem cell factor is covalently conjugated to a water soluble polymer.

100. [new] The method of claim 99 wherein the water soluble polymer is polyethylene glycol.

101. [new] The method of claim 97 or 98 wherein the stem cell factor is co administered with at least one other cytokine.

102. [new] The method of claim 99 wherein the stem cell factor is co administered with at least one other cytokine.

103. [new] The method of claim 101 wherein one or more cytokines are selected from a group consisting of Interleukin-1 (IL-1), Interleukin-2 (IL-2), Interleukin-3 (IL-3), Interleukin-4 (IL-4), Interleukin-5 (IL-5), Interleukin-6 (IL-6), Interleukin-7 (IL-7), Interleukin-8 (IL-8), Interleukin-9 (IL-9), Interleukin-10 (IL-10), Interleukin-11 (IL-11), Interleukin-12 (IL-12), erythropoietin (EPO), Granulocyte Colony-stimulating Growth Factor (G-CSF), Macrophage Colony-Stimulating Factor (M-CSF), Granulocyte-Macrophage Colony-Stimulating Factor (GM-CSF), Insulin-like Growth Factor-1 (IGF-1), and Leukemic Inhibitory Factor (LIF).

104. [new] The method of claim 102 wherein one or more cytokines are selected from a group consisting of IL-1, IL-2, IL-3, IL-4, IL-5, IL-6, IL-7, IL-8, IL-9, IL-10, IL-11, IL-12, EPO, G-CSF, M-CSF, GM-CSF, IGF-1, and LIF.

105. [new] The method of claim 97 wherein the pharmaceutically acceptable carrier is suitable for topical delivery.

106. [new] The method of claim 97 wherein the pharmaceutically acceptable carrier is suitable for oral delivery.

107. [new] The method of claim 97 wherein the pharmaceutically acceptable carrier is suitable for parenteral delivery.

108. [new] The method of claim 97 wherein the pharmaceutically acceptable carrier is suitable for pulmonary delivery.

109. [new] The method of claim 97 wherein the pharmaceutically acceptable carrier is suitable for nasal delivery.

110. [new] The method of claim 98 wherein the pharmaceutically acceptable carrier is suitable for topical delivery.

111. [new] The method of claim 98 wherein the pharmaceutically acceptable carrier is suitable for oral delivery.

112. [new] The method of claim 98 wherein the pharmaceutically acceptable carrier is suitable for parenteral delivery.

113. [new] The method of claim 98 wherein the pharmaceutically acceptable carrier is suitable for pulmonary delivery.

114. [new] The method of claim 98 wherein the pharmaceutically acceptable carrier is suitable for nasal delivery.

115. [new] The method of claim 98 wherein the hypopigmentation disorder is melanocytopenia.

116. [new] The method of claim 98 wherein the melanocytopenia is selected from the group consisting of vitilago and piebaldism.

REMARKS/ARGUMENTS

I. Preliminary Remarks and Status of the Claims

Claims 71-96 are under consideration in the instant application. These claims stand variously rejected under 35 U.S.C. §112 first paragraph, for allegedly lacking enablement and/or written description, and under 35 U.S.C. §112, second paragraph as supposedly being indefinite for failing to particularly point out and distinctly claim the invention. Applicants respectfully traverse the rejections. Applicants present new claims 97-116 directed to subject matter described in the specification and discussed in further detail herein below. These new claims do not add new matter to the specification.

II. Objections to the Specification

Applicants thank the Examiner for pointing out the sections of the specification that required updating for reference to SEQ ID NOs and the status of referenced applications. The above-presented amendment addresses the objections raised by the Examiner and Applicants request that the objections be withdrawn.

III. Rejection under 35 U.S.C. §112, first paragraph for lack of written description should be withdrawn.

Claims 75 to 84 and 91 to 96 were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which supposedly was not described in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention. Applicants respectfully disagree with the written description rejection and submit that the claims as amended are described in the specification in such a way as convey possession of the invention.

Claim 75 has been amended to recite:

A method of treating a hypopigmentation disorder in a human, the method comprising the step of administering to the human, a therapeutically effective amount of a stem cell factor (SCF) polypeptide, and optionally a pharmaceutically acceptable carrier.

The Examiner provided Applicants with express guidance, at page 11 of the Office action, that “a method of treating a hypopigmentation disorder. . .meets the written description provision of 35 U.S.C. §112, first paragraph.” Therefore, Applicants believe that claim 75 is described in the specification in full compliance with the written description requirements of 35 U.S.C. §112, first paragraph, and Applicants request that the rejection of claim 75 be withdrawn. Claims 76 to 84 and claims 90 to 96, variously depend from claim 75, and therefore the rejection of those claims also should be withdrawn for the same reasons.

IV. Rejection under 35 U.S.C. §112, first paragraph for lack of enablement should be withdrawn.

Claims 71-96 were rejected under 35 U.S.C. §112, first paragraph for assertedly lacking of enablement. The Examiner objected to the claims on three grounds. Applicants traversal of the rejections is based on the discussion below and on the submission presented January 10, 2003. Briefly summarizing the rejections, it appears to be the Examiner’s position that “not every single pigmentation disorder should be treated by SCF.” (Office action, page 6). In particular, the Examiner contends that *hyperpigmentation* disorders would not be as amenable to treatment by SCF as hypopigmentation disorders, which are described in the specification. Secondly, at page 7 of the Office action, the Examiner articulates a rejection of the claims because the specification does not provide “working examples that stimulate the growth of melanocyte *precursor* cells by administration of the SCF.” (*emphasis in original*, Office action, page 7). Thirdly, the Examiner indicates at page 8 of the specification that the specification “does not teach all possible variants of the SCF polypeptide of the instant invention. Applicants address each of the above points below and submit that the rejections are overcome.

With respect to the first ground for rejection, based on the comments on page 6, Applicants believe that rejection is directed to the subject matter of claims 75-84 and 91-96, as these are the claims, which, either independently or dependently, recite the term “pigmentation disorder.” Applicants have amended claim 75 to recite that the treatment method is for the treatment of a “hypopigmentation disorder.” As discussed in Section III above, this method is fully described by the specification as filed. As discussed in the previous response filed January

10, 2003 (incorporated herein by reference,) such a method of treatment also is enabled. More particularly, as corroborated by Costa *et al.*, (previously submitted) SCF represents a “therapeutic target for regulating the numbers and functional activity of . . . cutaneous melanocytes.” Figures 3 and 4 of that paper at page 2684 clearly demonstrate that injection of SCF results in pigmentation, and the authors indicate that SCF “promotes hyperpigmentation and enhanced melanization as well as mealnocyte hyperplasia.” From the studies in Costa *et al.* alone, it can be independently surmised that the inventors of the present invention were correct in teaching that SCF may be used in the “enhancement of growth of . . . neural crest derived melanocytes.”

Given the above cited teachings in the specification, those of skill in the art need only use routine methods of SCF delivery to achieve the desired therapeutic effect, because as the Federal Circuit has admonished, a specification need not teach, and preferably should omit, what is well known to those of skill in the art. *In re Buchner*, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). SCF is a novel cytokine that was identified by the present inventors. Those of skill in the art have been aware of methods of formulating and administering cytokines to individuals in need thereof before the priority date of the instant application. Optimizing such methods and formulations for use of the novel SCF compositions of the present invention would be a matter of routine considering that the level of skill in the art of cytokine therapeutics is high.

Moving to the rejection based on use of the term “melanocyte precursor cells.” Applicants believe this rejection is directed to claims 71-74 and 85-89, as these claims either independently or dependently are directed to methods of stimulating the growth of “melanocyte precursor cells.” Applicants believe the rejection is rendered moot in view of Applicants’ response to the 35 U.S.C. §112, second paragraph rejection of these claims, in which the term was reworted to recite “melanocyte cells.”

Finally, Applicants traverse the rejection of the claims articulated by the Examiner at pages 10 of the specification, where the Examiner raised objections to the use of variants of SCF in the claimed methods, indicating that it would require “undue experimentation . . . to culture hematopoietic progenitor cells with all possible SCF polypeptides.” The Examiner did, however, provide explicit guidance to the Applicants that “in other words, the specification is enabling for

a SCF polypeptide comprising at least amino acids 1-130 of SEQ ID NOs 46, 61, 63. . .” (Office action, page 9).

Initially, Applicants wish to clarify which claims this rejection appears to be directed towards. Applicants submit that claims 72, 74, 76 and 78, do not fall within the above rejection because they all recite fragments of sequences that are longer than 1-130 amino acids of the given SEQ ID NOs and are admitted by the Examiner as being enabled. With respect to claims 71 and 75, which recite that treatment is effected using “a stem cell factor (SCF) polypeptide,” Applicants discussed these claims with Examiner Bunner on September 22, 2003 and pointed out that this same language has been allowed in various sister applications, including *e.g.*, Claim 1 of U.S. Patent No. 6,207,454. Applicants submit that the specification adequately teaches those of skill in the art to treat a hypopigmentation disorder, or to stimulate the growth of melanocytes by administering a stem cell factor polypeptide. In view of the above, Applicants believe that the Examiner’s comments regarding “human SCF polypeptide 1-100; 1-110, 1-120, 1-123, 1-127, as set forth in Figures 42A-C and 44A-C or any other variant SCF polypeptides” (Office action, page 9) relate particularly to claims 73 and 77, which recites fragments smaller than 130 amino acids in length. While Applicants have amended claims 73 and 77 to remove recitation of 1-100, 1-110, 1-120, 1-123, 1-127, Applicants respectfully submit that the specification teaches how to make and use other SCF fragments *in addition to*, and other, than fragments that comprise at least amino acids 1-130 of stem cell factor polypeptides of sequences 46, 61 and 63 (see further discussion below).

The specification guides individuals to use SCF therapy to enhance the growth of melanocytes in hypopigmentation disorders, such as, vitiligo and piebaldism. Such treatment could readily be conducted by the skilled artisan using, *e.g.*, subcutaneous injection or even a topical administration of the therapeutic composition and determining whether pigmentation occurred. The specification further provides various animal model studies that demonstrate the efficacy and usefulness of SCF therapy see *e.g.*, page 29, line 9-25; FIG. 51; page 15, lines 20-31; see also Example 25, page 170, line 29 to page 175, line 35 and page 109, lines 2-4). For example, the specification teaches that “SCF treatment of mammals results in absolute increases in hematopoietic cells of both myeloid and lymphoid lineages,” (page 17 line 35-page 18, line 1) and provides detailed description of how to determine such increases *in vivo* Example 8 at pages

104 to 110. Thus, from the specification one of skill would readily be able to determine whether a given fragment of SCF will possess the desired activity, such as causing pigmentation at, for example, the site of administration of a subcutaneous injection of the given SCF fragment. Indeed, this is exactly how the authors of Costa *et al.* proceeded by administering a subcutaneous injection of SCF.

Further, the specification also teaches how to produce biologically active fragments of SCF, including but not limited to fragments that comprise amino acids 1-130 of SEQ ID NOs 46, 61 and 63. For instance, at page 185, the specification shows that SCF²⁻¹⁶⁴ or SCF⁵⁻¹⁶⁴ do possess some SCF activity. While it may be that such fragments have a “lowered activity” with respect to SCF¹⁻¹⁶⁴, there is still detectable stem cell factor activity associated with these fragments. It is not a requirement that the SCF fragments be as, or more, effective than the SCFs of the specific sequences exemplified in the specification, so long as the SCF fragments possess some SCF activity in stimulating the growth of melanocyte cells, because such fragments will still be useful in promoting the growth of such cells. Therefore, Applicants believe that it is inaccurate, and unduly limiting, to suggest that the specification teaches that only fragments “comprising amino acids 1-130 of SEQ ID NOs: 46, 61 and 63” possess the desired activity.

Moreover, as noted in the attached excerpt from Chapter 3 of a book entitled “Haemopoiesis: A Practical Approach” (*Eds.* Testa & Molineux, IRL Press, Oxford, U.K., 1993, see page 38) those of skill in the art have recognized that even if a given hematopoietic growth factor alone exerts a marginal or modest stimulatory effect, when combined with CSFs such a factor will have a synergistic stimulatory effect on hematopoietic cells. This is further corroborated by the instant specification in Example 21 (pages 156-160, especially, page 160, lines 8-33), which specifically states that SCF has a synergistic effect when combined with other hematopoietic growth factors. Thus, so long as the SCF fragments possess some SCF activity, they are contemplated to be useful and within the scope of the claims.

In view of the above comments, Applicants request that the rejection of claims 71-96 under 35 U.S.C. §112, first paragraph be withdrawn.

In addition to claims 71-96, applicants present herein above, new claims 97-98 which recite, in pertinent part that the SCF is a "polypeptide having the amino acid sequence of SEQ ID NO:44, SEQ ID NO: 46, or SEQ ID NO: 63, or biologically active fragments thereof that stimulate growth of hematopoietic progenitor cells." This is the exact language that has been allowed by Examiner Bunner from claim 71 of a sister application, U.S. Patent Application No. 09/635,251, which is directed to methods of preparing stem cell factor, and is based on the same specification as the instant application. The language of allowed claim 71 of that application is analogous to the language being presented for the current treatment methods in new claims 97-98. Therefore, Applicants believe that these claims of the present application are consistent with language that the Examiner would consider allowable. Applicants briefly discussed this issue with Examiner Bunner on September 22, 2003, and would like to invite the Examiner to contact the Applicants with further comments or suggestions regarding the newly presented claims. New claims 99-116, are analogous to claims 85-96, already pending in the instant application.

In light of the above remarks, Applicants believe the specification is enabled at least for methods that employ SCF or biologically active fragments of SEQ ID NOs: 46, 61 and 63. Applicants request withdrawal of the rejections of the claims based on 35 U.S.C. §112, first paragraph for lack of enablement and reconsideration of the claims for allowance.

V. Rejections under 35 U.S.C. §112, second paragraph are overcome by the amendments and should be withdrawn.

The Examiner rejected claims 71-74 and 79-89 under 35 U.S.C. §112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. More particularly, the Examiner rejected the claims for using the term "growth" in claims 71-74 and 79-89. The Examiner contended that it was not clear whether the term "growth" is intended to encompass proliferation or differentiation or both. Applicants submit that the term is intended to cover both proliferation of melanocytes and differentiation of melanocytes. As evidence that those of skill in the art would recognize this term to mean both, applicants cite back to the Examiner's characterization of the effects of SCF on melanocytes at page 6 of the Office action, where the Examiner states "SCF enhances melanocyte proliferation and differentiation." In order to further clarify this point, Applicants have amended claim 71 to replace the term "growth" with the phrase "proliferation or

differentiation,” thereby overcoming the rejection.

Applicants initially traverse the rejection of claims 71-74 and 79-89 based on the recitation of the term “melanocyte precursor cells,” as those of skill in the art would recognize that the SCF compositions of the invention would be useful in promoting the growth (proliferation and/or differentiation) of hematopoietic progenitor cells, and melanocyte precursor cells may be encompassed by such cells. However, in order to expedite prosecution of the instant claims, claim 71 has been amended to amend the phrase “melanocyte precursor cells” to “melanocyte cells.” This amendment, is supported by the specification at page 28, lines 3-5 of the specification, which provides that the SCF compositions of the invention are useful in the “enhancement of growth of . . . neural crest derived melanocytes.” Applicants believe this amendment removes the grounds for rejection.

In view of the foregoing response, Applicants submit that the outstanding rejection of the claims under 35 U.S.C. §112, second paragraph is overcome. Applicants request that the rejection be withdrawn and the claims be reconsidered for allowance.

VI. Request for Interview with Examiner Bunner

The undersigned representative thanks Examiner Bunner for the telephone conference on September 22, 2003 in which the above response was discussed. At that time, Examiner Bunner invited Applicants to file a response to the outstanding Office action and further indicated that she would be available to discuss the matter further upon review of this written submission, should such a discussion be necessary. Applicants respectfully submit that the above response overcomes the outstanding rejections. However, if upon review of the above response, the Examiner feels that a further discussion would facilitate allowance of the claims, Applicants request an interview with Examiner and therefore request that Examiner Bunner contact the undersigned representative.

VII. Concluding Remarks.

In view of the above amendments and remarks, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the

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Applicants respectfully request a withdrawal of the rejections and an indication of allowance of the application. Should the Examiner have any questions regarding this submission, she is cordially invited to contact the undersigned representative.

Dated: September 23, 2003

Respectfully submitted,

By 

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